

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO.
JAN-27

APPLICATION
NO. 101625.754

~~10/008,516~~

707000, 310

APPLICANT
Leventer et al.

CONFIRMATION NO.
Not yet assigned

FILING DATE
11/8/01

GROUP II

FEB 26 2002

RECEIVED

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
CFO	3,736,315	05/29/73	Kórösi et al.	260	239	03/04/71
z	4,322,346	03/30/82	Kórösi et al.	260	239	09/26/80
3	4,423,044	12/27/83	Kórösi et al.	424	244	02/25/82
4	4,614,740	09/30/86	Láng et al.	514	221	07/26/85
5	4,835,152	05/30/89	Kórösi et al.	514	220	08/20/87
6	5,204,343	04/20/93	Andrási et al.	514	221	10/17/91
7	5,459,137	10/17/95	Andrási et al.	514	220	06/21/93
8	5,521,174	05/28/96	Andrási et al.	514	220	06/07/95
9	5,519,019	05/21/96	Andrási et al.	514	220	06/07/95
10	5,639,751	06/17/97	Andrási et al.	514	220	06/07/95
11	5,795,886	08/18/98	Anderson et al.	514	220	02/11/97
12	5,891,871	04/06/99	Xia et al.	514	219	03/20/97
13	6,017,965	01/25/00	Mueller et al.	514	649	12/11/96
14	6,051,610	04/18/00	Mueller et al.	514	628	02/18/99
15	6,071,970	06/06/00	Mueller et al.	514	648	06/07/95
16	6,075,018	06/13/00	Vágó et al.	514	221	02/09/96
17	6,080,736	06/27/00	Landry et al.	514	221	12/07/99

R.D.T. Higley

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 <small>PATENT & TRADEMARK OFFICE</small>		FILING DATE 11/8/01	GROUP Not yet assigned 10014
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FOREIGN PATENT DOCUMENTS

EXAMINER

*Rod J. Haas
R.J. Haas*

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1/20/05

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		FILING DATE 11/8/01	GROUP Not yet assigned <u>1614</u>

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PATENT & TRADEMARK OFFICE*

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
<i>JH PTO</i>	S. Almquist et al., "Direct and Indirect Approaches to Enantiomeric Separation of Benzodiazepines Using Micro Column Techniques," <u>J. Chromatography A</u> , 679:139-146 (1994).
<i>25</i>	N. Bargmann-Leyder et al., "A Comparison of LC and SFC for Cellulose- and Amylose-Derived Chiral Stationary Phases," <u>Chirality</u> , 7:311-325 (1995).
<i>26</i>	A. Bond and M. Lader, "A Comparison of the Psychotropic Profiles of Tofisopam and Diazepam," <u>Eur. J. Clin. Pharmacol.</u> , 22:137-142 (1982).
<i>27</i>	M. Briley et al., "Tofisopam Enhances the Anticonvulsant Activity of Diazepam Against Some, but Not All, Convulsive Agents," <u>British J. Pharm.</u> , 82:300P (1984).
<i>28</i>	G. De Sarro et al., "GYKI 52466 and Related 2,3-benzodiazepines as Anticonvulsant Agents in DBA/2 Mice," <u>Eur. J. Pharmacol.</u> , 294:411-422 (1995).
<i>29</i>	I. Fellegvári et al., "Separation of Conformational Diastereomers of 2,3-Benzodiazepines by HPLC," <u>Chromatography in Symposia Biologica Hungarica</u> , H. Kalász and L.S. Ettre, Eds., 193-203 (1987).
<i>30</i>	V. Filip et al., "A Double-Blind, Placebo-Controlled Study with Tofizopam in Anxiety Neurosis," <u>Agressologie</u> , 22:27-30 (1981).
<i>31</i>	I. Fitov et al., "Separation of Enantiomers of Benzodiazepines on the Chiral-AGP Column," <u>J. Chromatography A</u> , 709:265-273 (1995).
<i>32</i>	E. Fogassy et al., "Studies on the Properties and Structure of Optically Active 1-(3,4-Dimethoxyphenyl)-4-Methyl-5-Ethyl-7,8-Dimethoxy-5H-2,3-Benzodiazepine (Tofizopam)," in <u>Bio-Organic Heterocycles</u> , H.C. van der Plas, L. Ötvös, and M. Simonyi, Eds., 229-233 (1984).
<i>33</i>	H. Goldberg et al., "Comparative Efficacy of Tofisopam and Placebo," <u>Am. J. Psychiatry</u> , 136:196-199 (1979).
<i>34</i>	K. Imre et al., "A Tofizopam (Grandaxin®) Farmakokinetikaja es Metabolizmusa," <u>Acta Pharmaceutica Hungarica</u> , 63:83-90 (1993).
<i>35</i>	C. Ito, "Behavioral Pharmacological Study on the Structure Activity Relationship of Benzodiazepine Derivatives: with Particular Reference to the Activity of 2,3-Benzodiazapine," <u>J. Tokyo Med. College</u> , 39:369-384 (1981).
<i>36</i>	J. Kanto et al., "Tofizopam: a Benzodiazepine Derivative without Sedative Effect," <u>Intl. J. Clin. Pharm. Ther. Tox.</u> , 20:309-312 (1982).
<i>37</i>	K. Maier et al., "The Effect of Tofisopam on Psychic Performance in Persons With More Than Average Anxiety: A Controlled Experimental Trial," <u>Current Therapeutic Research</u> , 35(4):541-548 (1984).
<i>38</i>	"Tofisopam", <u>Martindale, Royal Pharmaceutical Society of Great Britain</u> , p. 620, col. 1 (1993).

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Rolf H. Haas

DATE CONSIDERED

*8/4/04
11/2/03*

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FEB 01 2002
PATENT & TRADEMARK OFFICE*

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
<i>CTO</i>	T. Mennini et al., "Brain Levels of Tofisopam in the Rat and Relationship with Benzodiazepine Receptors," <u>Arch. Pharmacol.</u> , 321:112-115 (1982).
<i>37</i>	J. Molcan et al., "Tofizopam in the Therapy of Anxious-Depressive Syndroms," <u>Agressologie</u> , 22:23-24 (1981).
<i>40</i>	F. Pal, "A Grandaxin® Gyógyszertechnológiája," <u>Acta Pharmaceutica Hungarica</u> , 63:67-78 (1993).
<i>41</i>	Pakkanen et al., "Comparative Study of the Clinical Effects of Tofizopam, Nitrazepam and Placebo as Oral Premedication," <u>British J. Anaesthesia</u> , 1009-1012 (1980).
<i>42</i>	S. Pellow and S. File, "The Effects of Tofisopam, a 3,4-Benzodiazepine, in Animal Models of Anxiety, Sedation, and Convulsions," <u>Drug Dev. Res.</u> , 7:61-73 (1986).
<i>43</i>	L. Petócz and I. Kosóczky, "The Main Pharmacological Characteristics of Grandaxin (Tofisopam, EGYT-341)," <u>Ther. Hungarica</u> , 23:134-138 (1975).
<i>44</i>	L. Petócz, "The Pharmacological Effects of Tofisopam (Grandaxin)®, <u>Acta Pharmaceutica Hungarica</u> , 63:79-82 (1993).
<i>45</i>	V. Saano and A. Urtti, "Tofizopam Modulates the Affinity of Benzodiazepine Receptors in the Rat Brain," <u>Pharm. Biochem. Behavior</u> , 17:367-369 (1982).
<i>46</i>	V. Saano, "Tofisopam Selectively Increases the Action of Anticonvulsants," <u>Med. Biol.</u> , 64:201-206 (1986).
<i>47</i>	V. Saano et al., "Tofisopam Enhances the Action of Diazepam Against Tremor and Convulsions," <u>Med. Biol.</u> , 61:49-53 (1983).
<i>48</i>	T. Seppälä et al., "Tofisopam, a Novel 3,4-Benzodiazepine: Multiple-Dose Effects on Psychomotor Skills and Memory. Comparison with Diazepam and Interactions with Ethanol," <u>Psychopharmacology</u> , 69:209-218 (1980).
<i>49</i>	M. Simonyi and I. Fitov, "Stereoselective Binding of a 2,3-Benzodiazepine to Human Serum Albumin," <u>Biochemical Pharmacology</u> , 32(12):1917-1920 (1993).
<i>50</i>	R. Sladká et al., "A Placebo-controlled Clinical Trial With Tofizopam in the Treatment of Anxiety Neurosis," <u>Ther. Hungarica</u> , 27:176-180 (1979).
<i>51</i>	J. Szegő et al., "Selected Passages From the Clinical-Pharmacological and Clinical Trials of Grandaxin®, <u>Acta Pharmaceutica Hungarica</u> , 63:91-98 (1993).
<i>CTO</i>	<i>52</i>

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R.D.J.H.J. Jr.

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*8/4/04**11/10/03*

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
CTD 53	G. Toth et al., "Racemate Splitting of (+)-5-ethyl-1-(3,4-dimethoxyphenyl)-6,7-dimethoxy-4-methyl-5H-2,3-benzodiazepine an Anomalous Chiroptic Behavior of Enantiomer (1)," <u>J. Heterocyclic Chem.</u> , 20:709-713 (1983).
54	G. Váradyi et al., "The Clinical Evaluation of Grandaxin Used in the Treatment of Outpatients (A Multicentric Study)," <u>Ther. Hungarica</u> , 23:153-158 (1975).
55	J. Visy and M. Simonyi, "The Role of Configuration and Conformation in the Binding of 2,3-Benzodiazepines to Human Serum Albumin," <u>Chirality</u> , 1:271-275 (1989).
CTD 56	F. Zsila et al., "Separation and Identification of Tofisopam and Stereoisomers by Hyphenated HPLC-CD Technique," <u>J. Liq. Chrom. & Rel. Technol.</u> , 22:713-719 (1999).

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Rd. H. Ho
*Chris D. Stamps*8/4/04
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